



NOV - 3 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Boston Scientific Corporation  
% Ms. Angela Byland  
Manager, Regulatory Affairs  
Cardiovascular  
Two Scimed Place  
Maple Grove, Minnesota 55311-1566

Re: K021901

Trade/Device Name: Wallgraft® Tracheobronchial Endoprosthesis with Unistep Plus  
Delivery System

Regulation Number: 21 CFR 878.3720

Regulation Name: Tracheal prosthesis

Regulatory Class: II

Product Code: JCT

Dated: June 7, 2002

Received: June 10, 2002

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of July 9, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

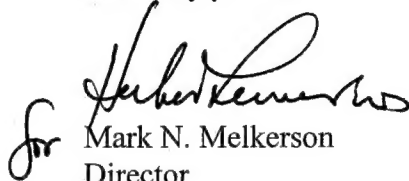
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a printed name. To the left of the signature is a small, stylized handwritten mark that looks like "for".

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## Indications for Use Statement

510(k) Number  
(if known)

K021901

Device Name

WALLGRAFT® Tracheobronchial Endoprosthesis with  
Unistep™ Plus Delivery System

Indications For Use

The WALLGRAFT® Tracheobronchial Endoprosthesis is  
indicated for use in the treatment of tracheobronchial  
strictures produced by malignant neoplasms.

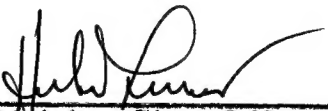
Prescription Use:   X    
(Per 21 CFR §801 Subpart D)

OR

Over-The-Counter Use: \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K021901

**510(k) Summary**  
**K021901****Submitter's  
Name and  
Address**

Boston Scientific Corporation  
One Scimed Place  
Maple Grove, MN 55311

**Contact Name  
and Information**

Angela Byland  
Manager, Regulatory Affairs  
Phone: 763-494-2887  
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**Original Date  
Prepared**

June 7, 2002

**Date Prepared**

July 14, 2006

**Proprietary  
Name(s)**

WALLGRAFT® Tracheobronchial Endoprosthesis with  
Unistep™ Plus Delivery System

**Common Name**

Tracheal Endoprosthesis

**Product Code**

JCT

**Classification of  
Device**

Class II, 21 CFR Part 878.3720

**Predicate Device**

|  |         |              |
|--|---------|--------------|
| WALLGRAFT®<br>Tracheobronchial<br>Endoprosthesis<br>with Unistep™<br>Delivery System | K000001 | June 5, 2005 |
|--|---------|--------------|

|  |         |                   |
|--|---------|-------------------|
| WALLGRAFT®<br>Tracheobronchial<br>Endoprosthesis<br>with Unistep™<br>Delivery System | K003100 | December 20, 2000 |
|--|---------|-------------------|

## Device Description

The Wallgraft Endoprosthesis with Unistep Plus Delivery System is available in the models indicated in the table below.

A brief description of the stent graft and delivery system components follow.

| Stent Graft Diameter | Stent Graft Length         | Delivery System Profile |
|----------------------|----------------------------|-------------------------|
| 6.0 mm               | 20 mm, 30 mm, 50 mm, 70 mm | 9F                      |
| 7.0 mm               | 20 mm, 30 mm, 50 mm, 70 mm | 9F                      |
| 8.0 mm               | 20 mm, 30 mm, 50 mm, 70 mm | 9F                      |
| 9.0 mm               | 20 mm, 30 mm, 50 mm, 70 mm | 10F                     |
| 10.0 mm              | 20 mm, 30 mm, 50 mm, 70 mm | 10F                     |
| 12.0 mm              | 30 mm, 50 mm, 70 mm        | 11F                     |
| 14.0 mm              | 50 mm, 70 mm               | 12F                     |

## Stent Graft Description

The Wallgraft Endoprosthesis (stent graft) consists of a metallic stent comprised of biomedical superalloy monofilament wire with a radiopaque core, braided in a tubular mesh configuration. A platinum nickel micro-cable is incorporated into the stent to enhance radiopacity of the device. A graft material comprised of braided polyester yarn (PET) is adhesively bonded to the outside of the metallic stent. This design configuration results in a stent graft that is flexible, compliant, and self-expanding with the barrier characteristics of a tubular graft.

## Delivery System Description

The Unistep Plus Delivery System consists of a coaxial tube system. The exterior tube serves to constrain the stent graft over the interior tube until retracted during deployment. The coaxial tubes have the capability of re-constraining the stent graft after partial deployment. A holding sleeve and stent cup, attached to the interior tube, aid in the re-constraining process.

Radiopaque marker bands situated adjacent to the proximal and distal ends of the stent graft facilitate imaging during deployment. A radiopaque marker band located on the exterior tube and a limit marker band on the interior tube function as deployment limit markers. Re-constraint is possible up to the point where the exterior tube marker band is proximally retracted to the location of the interior tube limit marker.

The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035" guide wire. The delivery system will be available in a single working length of 90 cm.

## Intended Use

The WALLGRAFT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

## Technological Characteristics

The modified 9 F - 11 F Unistep Plus Delivery System of the 6 mm to 12 mm Wallgraft Endoprosthesis will be manufactured in a substantially equivalent manner to the currently marketed 12 F delivery system of the 14 mm Wallgraft Tracheobronchial Endoprosthesis with Unistep Plus Delivery System, cleared to market under K003100, December 20, 2000.

## Performance Testing

Testing was conducted to verify that the modified 9 F - 11 F delivery system met product specifications. The following testing was performed:

- Total Catheter Length
- Catheter Crossing Profile
- Deployment Force
- Reconstraintment Force
- Stent Graft Securement
- Hub to Stainless Steel Tube Tensile
- Distal Tip Tensile
- Inner Member Assembly Tensile
- Valve Body to Exterior Tube Tensile
- Deployed Stent Graft OD
- Post Accelerated Aging Testing
- Biocompatibility

All test results verified that the modified 9 F - 11 F delivery system is adequate for its intended use. The modified device is considered substantially equivalent to the currently marketed 9 F - 11 F delivery system (K000001) and the 12 F delivery system (K003100).

## Conclusion

In summary, Boston Scientific Corporation has demonstrated that the WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System is substantially equivalent based on design, test results, and indications for use to the predicate devices.